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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,620	02/20/2004	Liwen Jiang	14769US02	7208

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,620	JIANG ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,13,15 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-9,13,15 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/20/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 20, 2007 has been entered.

Status of Objections and Rejections

2. Office acknowledges the receipt of Applicant's request for continued examination (RCE) filed on July 20, 2007. All previous rejections not set forth below have been withdrawn in view of claim amendments. Claims 1, 7-9, 13, 15, and 17-29 are pending. Claims 1, 7-9, 13, 15, and 17-29 are examined on merits in this Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3, 7-9, 13, 15, and 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (The Journal of Cell Biology, 143:1183-1199, 1998) in view of Zheng et al. (Plant Physiol., 109:777-786, 1995) and Goddijn et al. (Trends Biotechnol. 13: 379-387, 1995).

Jiang et al. teach a DNA construct comprising a promoter sequence (35S) that is capable of expression in plant seed, operably linked with a first DNA sequence encoding proaleurain (target protein), which is operably linked with a second DNA sequence having a transmembrane domain (TMD) derived from BP-80 or α-TIP protein and a cytoplasmic tail (CT) sequence derived from BP-80 or α-TIP protein, wherein second nucleic acid sequence serve as anchors for delivering the target proteins to subcompartments of protein storage vacuoles of the cells. The second nucleic acid is operably linked with a third nucleic acid that functions as transcription region (NOS terminator in pBI221 vector). The spacer sequence taught in the reference encodes an amino acid sequence which has 100% sequence identity to instant SEQ ID NO: 8. The reference further teaches that subcompartments comprise globoids or crystalloids and construct comprising a spacer sequence operably linked to 5' end of TMD. The reference further teaches a proteolytic cleavage sequence Kex2 between 3' end of target protein sequence and 5' end of TMD. The reference further teaches association of protease activity within protein storage vacuole that acts on the proteolytic cleavage sequence so that target protein separates from the transmembrane domain. The reference further teaches proaleurain signal peptide sequence present at the 5' end of target sequence (proaleurain). The DNA construct taught in the reference was used to

transform tobacco suspension culture protoplasts. See in particular, page 1183, abstract; page 1184, column 2nd through the end of first paragraph of column 1st of page 1185; page 1186, results, figure 1; page 1187, table 1; page 1188, figure 2; page 1189, figures 3 and 4; page 1190, figure 5; page 1191, table II, figure 6; page 1192, figure 7; page 1194, table III; page 1196, figure 10.

Jiang et al. do not teach a glutelin Gt1 promoter.

Zheng et al. teach a seed storage protein glutelin Gt1 gene promoter. The reference further teaches that said promoter directed the expression of phaseolin (gene of interest) in a seed-specific manner. The transgenic seed storage protein phaseolin accumulated up to 4% in vacuolar protein bodies of transgenic rice seeds. The reference clearly lays emphasis on using glutelin Gt1 gene promoter in obtaining high and stable expression of a foreign protein of interest in the transgenic seeds. See in particular, page 777, abstract; page 778, materials and methods; page 780, Figures 1 and 3; page 781, figures 4 and 5; page 782, figures 6 and 7; page 783 figure 8; page 784, figure 9.

Goddijn et al. (Trends Biotechnol. 13: 379-387, 1995) teach that it is well known in the art that seeds can also be used as "bioreactors" for the production of pharmaceutically or industrially important products. See the entire article.

It would have been prima facie obvious to one skilled in the art at the time the claimed invention was made to modify Jiang et al. DNA construct by operably linking any target coding sequence encoding a protein of interest to any seed-specific promoter including the seed-specific glutein Gt1 promoter of Zheng et al. for the purpose of using

the modified DNA construct to transform Jiang et al. tobacco cells or Zheng et al. rice cells. It would have been obvious for one of ordinary skill in the art to use any method of plant transformation including *Agrobacterium tumefaciens* Ti plasmid system based plant transformation method of Zheng et al. to obtain transgenic plants and seeds thereof which express said target protein of interest.

Given that Goddijn et al. teach that seeds can be used as "bioreactors" for the production of pharmaceutically or industrially important products, and Zheng et al. teach that glutelin Gt1 promoter has the property of directing stable and high levels of seed-specific expression of a coding sequence encoding a protein of interest, one of the ordinary skill in the art would have been motivated to express the modified DNA construct of Jiang et al. in any plant cell including tobacco cells of Jiang et al. or rice cells of Zheng et al. to obtain transgenic plants and seeds derived thereof which express high levels of a target protein of interest with reasonable expectation of success.

In the response filed in the paper of July 20, 2007, Applicants argue that construct of claim 1 is very special construct having α-TIP CT sequence which would be particularly useful in bypassing the Golgi functions that generate complex N-glycans. Applicants further argue that the protein of interest is not any protein of interest but should be one being directed to the PSV crystalloid via a direct ER-PSV pathway (response, page 7, lines 6-10). Applicants further argue that there is no teaching or suggestion in the prior art of record (including Jiang et al.) that proteins expressed in seeds with a seed specific promoter can be successfully directed by the α-TIP CT

sequence bypassing the Golgi into a PSV crystalloid. Applicants further argue that it would not be obvious for one of ordinary skill in the art to modify the construct of the Jiang et al. with glutelin Gt1 promoter and reasonably expect the success of the modification (response, page 7, lines 16-26).

Applicant's arguments were fully considered but were not found to be persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., PSV crystalloid, ER-PSV pathway etc.) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Nevertheless, it is also important to note that Jiang et al. clearly teaches that protein of interest would be directed to the PSV crystalloid via a direct ER-PSV pathway.

Furthermore, it is important to note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Jiang et al. teach all the elements required to practice the invention, except the seed-specific glutelin Gt1 promoter. Zheng et al. provides motivation for using glutein Gt1 promoter to obtain high expression and stable accumulation of foreign protein of interest in vacuolar

protein bodies, and Goddijn et al. clearly teach the importance of using seeds as bioreactors in expressing any protein of interest. Thus it would have been within the scope of an ordinary skill in the art to combine the teachings of Jiang et al., Goddijn et al. and Zheng et al. to arrive at the instantly claimed invention with reasonable expectation of success.

Thus it is maintained that the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art.

Conclusions

4. Claims 1, 7-9, 13, 15, and 17-29 remain rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER